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Quality of Care and Outcomes Assessment

A SYSTEMATIC REVIEW OF MAJOR NON-INFERIORITY CARDIOVASCULAR TRIALS FROM 2006-2011

Poster Contributions
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Background: Non-inferiority trials can test if two clinical strategies have similar clinical effectiveness. Since the tested new interventions may have safety or tolerability advantages (such as the case for novel anticoagulants), non-inferior efficacy might suffice for introducing them into clinical practice. We investigated the characteristics and recent trends in publications of non-inferiority cardiovascular trials and their criteria for non-inferiority.

Methods: We conducted a systematic review of cardiovascular trials published in NEJM, Lancet, and JAMA from Jan 2006-Dec 2011. We identified trials that tested for non-inferiority of the primary outcome for an intervention when compared with an active control. For trials with factorial design or manuscripts reporting more than one trial, we did one abstraction per each primary hypothesis.

Results: We screened 873 citations and identified 39 non-inferiority trials (24 drug trials, 13 device trials, 2 others). Non-inferiority trials publications were stable over time (there were 7,4,7,7,7, and 7 trials from 2006 through 2011, P=0.44 for trend). The median sample size was 3153 (IQR: 707-6706) and the median calculated power to prove non-inferiority was 90% (IQR: 80%-91%). The median non-inferiority margin was 7.5% (IQR: 4%, 25%; range: 1% -105.4%).The majority of non-inferiority trials were funded exclusively (72%; n=28) or partially (18%; n=7) by industry. Overall, 69.2% trials (n=27) met the non-inferiority criteria while 23.1% (n=9) did not, and 7.7% (n=3) showed significantly worse results with the tested intervention. In one trial, there were significantly higher deaths in the intervention arm.

Conclusions: Our results indicate that non-inferiority trials are primarily designed by the industry to test new treatment options. Such trials, not infrequently, failed to prove non-inferiority and were at times associated with safety concerns. Wide variations exist across trials for designating the margin of non-inferiority, with some trials considering an intervention with half the efficacy of standard therapy to have non-inferior efficacy.